

AUG 16 1996

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IVY BIOMEDICAL SYSTEMS, INC.

510(K) SUMMARY

Ivy Biomedical Systems, Inc.
11 Business Park Drive
Branford, CT 06405
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Contact: Dick Listro

Prepared: 10/12/95

Classification Name: Patient Monitor
Common Name: Patient Monitor
Proprietary Name: Model 405P

This Summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807-92.

Substantial Equivalence

The Model 405P physiological monitor is the same in function and operation as the F.D.A. approved Ivy Biomedical Systems Model 405T physiological monitor, with the following exceptions:

- The replacement of the flat panel electroluminescent display with a Liquid Crystal Display and LED's for numerics
- The deletion of the option to monitor Temperature.
- The deletion of the option to monitor invasive blood pressure.


These exceptions have no adverse effect on the safety or effectiveness of the device when used as labeled.

The Models 405T and 405P patient monitors are both adult or neonate monitors

The 405P monitors the following parameters:

ECG, Heart Rate, Pulse Oximetry and Non-Invasive Blood Pressure.

The Models 405T and 405P are both intended for use in Emergency Room, Surgery, Recovery Room, Intensive Care and surgical applications.


Signature

11/21/95
Date

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